

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 02N-0288]

Medical Devices; Designation of Special Control for Eight Surgical Suture Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the classification regulations for eight surgical suture devices previously reclassified into class II, in order to specify a special control for those devices. FDA is proposing the guidance document “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA” as the special control that the agency believes will reasonably assure the safety and effectiveness of the devices, and FDA is announcing the availability for comment of that guidance document elsewhere in this issue of the **Federal Register**. Elsewhere in this issue of the **Federal Register**, FDA is also publishing a final rule reclassifying the absorbable polydioxanone surgical (PDS) suture from class III (premarket approval) to class II (special controls), and is designating as the special control for that device, effective immediately, the same guidance document here proposed as the special control for the eight surgical sutures devices covered by this proposed rule. After public comments are reviewed, FDA intends to issue a final rule for the eight surgical sutures covered by this proposed rule, making the guidance effective as the special

control guidance for those sutures in addition to the PDS suture. Following the effective date of such final rule, any firm submitting a premarket notification (510(k)) for a new surgical suture will need to address the issues covered in the special control guidance. However, the firm needs only to show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

DATES: Submit written or electronic comments on the proposed rule by [*insert date 90 days after date of publication in the **Federal Register***]. See section VI of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Anthony D. Watson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101-629), and the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for

human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance.

SMDA broadened the definition of class II devices to mean those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

The 1976 amendments also broadened the definition of “device” in section 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified into class III all transitional devices, i.e., those devices previously regulated as new drugs, including surgical sutures.

In the **Federal Register** of December 16, 1977 (42 FR 63472), FDA published a notice that identified sutures as class III devices under the transitional provisions of the act. Section 520(l)(2) of the act (21 U.S.C.

360j(l)(2)) provides that the manufacturer or importer of a device classified in class III under the transitional provisions may file a petition for reclassification of the device into class I or class II. Procedures for filing and review of classification petitions are set forth in § 860.136 (21 CFR 860.136).

II. Regulatory History of the Devices

In accordance with section 520(l)(2) of the act and § 860.136, FDA, after consulting with members of the General and Plastic Surgery Devices Panel, reclassified certain surgical suture devices in part 878 (21 CFR 878) from class III to class II as follows:

1. Absorbable poly(glycolide/L-lactide) surgical suture (§ 878.4493), reclassification order (letter) dated September 14, 1989;
2. Stainless steel suture (§ 878.4495), reclassification order (letter) dated July 30, 1986;
3. Absorbable surgical gut suture (§ 878.4830), reclassification order (letter) dated September 19, 1988;
4. Nonabsorbable poly(ethylene terephthalate) surgical suture (§ 878.5000), reclassification order (letter) dated July 5, 1990;
5. Nonabsorbable polypropylene surgical suture (§ 878.5010), reclassification order (letter) dated July 5, 1990;
6. Nonabsorbable polyamide surgical suture (§ 878.5020), reclassification order (letter) dated February 15, 1990;
7. Natural nonabsorbable silk surgical suture (§ 878.5030), reclassification order (letter) dated November 9, 1990; and
8. Nonabsorbable expanded polytetrafluoroethylene surgical suture (§ 878.5035), reclassification order (letter) dated September 9, 1999.

III. Proposed Rule

FDA is proposing to amend the classification regulations for the foregoing eight surgical suture devices in order to designate a special control for each device. With the exception of the nonabsorbable expanded polytetrafluoroethylene surgical suture, all of the transitional surgical suture devices were reclassified before the provisions of SMDA became effective that broadened the definition of class II devices to establish special controls beyond performance standards. Thus, developing device-specific guidance as the means to provide reasonable assurance of the safety and effectiveness of the device was not a regulatory option at the time of their original reclassification. No mandatory performance standard has been developed for these devices.

Nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical sutures were reclassified from class III to class II (special controls) and special controls were identified, including device-specific labeling and FDA-recognized consensus standards.

FDA has developed a guidance document for surgical suture devices and, under the SMDA authority, is now proposing to apply it as the special control the agency believes will reasonably assure the safety and effectiveness of these devices. FDA is identifying the guidance document entitled “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA” as the proposed special control. The special controls included in the guidance document are the same as those identified in the Code of Federal Regulations (CFR) for ePTFE surgical sutures with one exception. The consensus standard identified in 21 CFR 878.5035 as United States Pharmacopoeia (U.S.P.) 21 has been updated in the guidance to “the currently recognized USP standard” to reflect the fact that the compendium of U.S.P.

standards is now published yearly. In the past, it was published only every 5 years, U.S.P. 21 having been the 1985 publication.

IV. Risks to Health

FDA has identified the following risks to health associated with the use of surgical sutures: Improper selection and use, suture breakage, adverse tissue reaction, and infection.

A. Improper Selection and Use

Proper selection of the size and type of suture most suitable for the type of tissue and surgical site depends on the performance of the suture, the material composition, absorbability (and if absorbable, the rate of absorption), tensile strength (and changes in tensile strength over time), and/or specific instructions for certain types of sutures, tissues, or surgical sites (e.g., “Prolonged contact with bile or urine may result in calculus formation.”).

Improper selection and use can result in:

- Wound dehiscence (splitting open of the sutured tissue),
- Unsatisfactory appearance of the surgical scar, or
- Impaired function or mobility at the surgical site.

Any of these events may result in the patient having to undergo another surgical procedure.

B. Suture Breakage

The intended use of a surgical suture is to successfully hold tissue together until healing is sufficiently complete. Suture breakage before the sutured wound heals can result in wound dehiscence. This may interfere with the normal healing process and/or result in the patient having to undergo another surgical procedure.

C. Adverse Tissue Reaction

An adverse tissue reaction to the surgical suture is a potential risk to health generally associated with all surgical sutures if biocompatibility, toxicity, and immunogenicity of the sutures are not adequately addressed. An adverse tissue reaction may result from:

- Foreign body reaction to the suture material;
- Toxicity of nonbiocompatible materials (dyes, coatings);
- Cytotoxic levels of sterilization residues;
- Absorbable suture materials that are absorbed too quickly or too slowly, producing a toxic response; or
- A local or systemic allergic reaction in patients with an abnormal sensitivity to the suture material, dye or coating.

D. Infection

Infection is a potential risk to health generally associated with all surgical procedures and implanted devices. Infection can result from:

- Inadequate sterilization of the surgical suture,
- Failure of the packaging to maintain sterility, or
- Contamination after the package is opened.

Preventative measures, including implantation of a sterile device and strict adherence to accepted sterile technique are the best defenses against infection.

V. Special Controls

FDA believes that in addition to general controls, the class II special control guidance document entitled “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA” is an adequate special control to address the risks to health associated with surgical sutures

and thus provide reasonable assurance of the safety and effectiveness of the device. The class II special controls guidance document provides information on how to meet premarket notification (510(k)) submission requirements for surgical sutures, including recommendations regarding device description, preclinical data, clinical data, color additives, sterilization, and labeling. It identifies voluntary consensus standards that address surgical suture specifications and performance, material biocompatibility and sterilization, and FDA guidance documents that address material biocompatibility and sterilization:

The class II special controls guidance document addresses the risks to health associated with surgical sutures in the following four ways:

- Adherence to the labeling recommendations in the guidance addresses the risk of improper suture selection and use by ensuring that users have adequate information on suture performance, material composition, absorbability (and if absorbable, the rate of absorption) and changes in tensile strength over time, to select the proper size and type of suture for the type of tissue and surgical site;
- Adherence to the voluntary consensus standards recommended in the guidance addresses the risk of surgical suture breakage by ensuring that surgical sutures have adequate tensile strength, diameter, and needle attachment strength;
- Adherence to the biocompatibility testing recommendations and biocompatibility standards in the guidance addresses the risk of an adverse tissue reaction by ensuring that the surgical sutures are made of materials with adequate biocompatibility and that the absorbable surgical suture materials have appropriate pharmacokinetic properties; and

- Adherence to the sterilization guidance and the voluntary consensus standards recommended in the guidance document addresses the risk of infection by ensuring that the surgical suture is sterile and has adequate packaging to maintain sterility.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the guidance document entitled “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” This guidance document is proposed as the special control for these eight surgical sutures and is not yet final or in effect as to these sutures. After public comments on this proposed rule and on the guidance document are reviewed, FDA intends to issue a final rule for these eight surgical sutures and the guidance document will become final and effective as the special control guidance for them. Following the effective date of such final rule, any firm submitting a premarket notification (510(k)) for a new surgical suture will need to address the issues covered in the special control guidance. However, the firm needs only to show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness. Also, elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying the absorbable PDS suture from class III (premarket approval) to class II (special controls), and designating the same guidance document as the special control for that device. The special control guidance document is immediately in effect as the special control for the PDS suture only, but as to that suture remains subject to public comment and possible future revision under the agency’s good guidance practices.

VI. Proposed Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

VII. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act 5 U.S.C. 601–612, and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The special controls guidance document does not impose any new burdens on manufacturers of these devices. FDA has granted 201 substantial

equivalence orders from 95 manufacturers of these devices in the last 10 years. The guidance document is based upon the review of the information submitted in these premarket notifications. Based on the review of the premarket notifications, FDA believes that manufacturers presently marketing these devices are in conformance with the guidance document and they will not need to take any further action, if this rule is finalized. The guidance document merely assures that, in the future, devices of these generic types will be at least as safe and effective as the presently marketed devices. These devices are already subject to premarket notification and labeling requirements. The guidance document advises manufacturers on appropriate means of complying with these requirements.

The consensus standards in the guidance were recognized under section 514(c) of the act (21 U.S.C. 360d(c)) for the purpose of demonstrating certain aspects of substantial equivalency. The manufacturer may provide a declaration of conformity to a recognized standard to meet a premarket notification requirement. Ordinarily, this will provide a simplified method of meeting the requirement. The manufacturer may choose to submit other data or information to meet the requirement. The guidance document sets out options that the manufacturer has in this respect.

For the foregoing reasons, the agency certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

The information collections addressed in the special control guidance document identified by this proposed rule have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120).

X. Submission of Comments

You may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance by [*insert date 90 days after date of publication in the **Federal Register***]. You should submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. The guidance document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 878.4493 is amended by revising paragraph (b) to read as follows:

§ 878.4493 Absorbable poly(glycolide/L-lactide) surgical suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” See § 878.1(e) for the availability of this guidance document.

3. Section 878.4495 is amended by revising paragraph (b) to read as follows:

§ 878.4495 Stainless steel suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” See § 878.1(e) for the availability of this guidance document.

4. Section 878.4830 is amended by revising paragraph (b) to read as follows:

§ 878.4830 Absorbable surgical gut suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Surgical

Sutures; Guidance for Industry and FDA.” See § 878.1(e) for the availability of this document.

5. Section 878.5000 is amended by revising paragraph (b) to read as follows:

§ 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” See § 878.1(e) for the availability of this document.

6. Section 878.5010 is amended by revising paragraph (b) to read as follows:

§ 878.5010 Nonabsorbable polypropylene surgical suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” See § 878.1(e) for the availability of this document.

7. Section 878.5020 is amended by revising paragraph (b) to read as follows:

§ 878.5020 Nonabsorbable polyamide surgical suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” See § 878.1(e) for the availability of this guidance document.

8. Section 878.5030 is amended by revising paragraph (b) to read as follows:

§ 878.5030 Natural nonabsorbable silk surgical suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” See § 878.1(e) for the availability of this guidance document.

9. Section 878.5035 is amended by revising paragraph (b) to read as follows:

§ 878.5035 Nonabsorbable expanded polytetrafluoroethylene surgical suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." See § 878.1(e) for the availability of this guidance document.

Dated: October 16, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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